K072667

Executive Summary

OCT 1 0 2007

Company Name:	Solutions Inc.
Company Address	3600 Chamberlain Lane, Ste. 104 Louisville, KY 40241
Telephone:	(502) 228-2901
Fax:	(502) 228-2931
Contact Person:	Victor Anderson

Summary Preparation Date: July 27, 2007

Trade Name: *Sharps Away Disposable Containers*

Common Name: Sharps Container

Classification Name: Container, Sharps

Predicate Device Identification:
CFR21 880.5570
Sharps Container
Product Code: MMK
Device Class: II

Legally Marketed Equivalent Device:

Company	*Product*	*510(k) #*
Becton Dickinson	B-D Guardian Nestable Sharps Collectors	K943575

Description:
Sharps Away Disposable Containers are injection molded polypropylene plastic. The containers are closable, puncture resistant, leak proof on the sides and bottom and stable. The label, containing an overfill warning and an easily visible fill line, is adhered to the container at the factory. The containers are translucent and are red and yellows. The label is white with the biohazard warning fluorescent orange.

Sharps Away Disposable Containers are available in a variety of sizes. Each product has two parts, which assemble together to form a unit. Assembly is easily visualized. They can be nested together to reduce storage space.

Handles are present on the 2-quart, 5-quart, 2.5-gallon and the 6-gallon containers. They are strong, easy to grasp and permits control of the container with one hand. Wall brackets are available for the 2-quart, 5 quart and the 2.5-gallon size. A counter top holder is available for the 1-quart size.

The Sharps Away Disposable Containers meet or exceeds OSHA recommendations for sharps containers.

Intended Use:

Sharps Away Disposable Containers are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps.

Predicate Product Comparison Table:

Manufacturer	Solutions Inc	Becton Dickinson
Trade Name	Sharps Away Disposable Container	B-D Guardian Nestable Sharps
K Number		K943575
Indication for Use	Sharps Away Disposable Containers are intended to be used for the safe disposal of hazardous sharps	B-D sharps containers are intended to be used for the safe disposal of hazardous sharps
Target population	Healthcare professional	Healthcare professional
Where used	Healthcare facilities	Healthcare facilities
Material	polypropylene	polypropylene
Sharps access	Sharps inserted through the top in a vertical position with sharp side down through the hole formed with flaps through which the sharp is inserted	Sharps inserted through the top in a vertical position with sharp side down through the hole formed with flaps through which the sharp is inserted
Sharps closure	Flaps are closed and locked in place for removal	Flaps are closed and locked in place for removal
Impact Resistance	Yes	Yes
Puncture Resistance	Yes	Yes
Leak resistance:	Yes	Yes
Single Use:	Yes	Yes
Non-sterile:	Yes	Yes

Substantial Equivalence Discussion of Similarities and Differences:
The Sharps Away Disposable Containers are similar to the B-D Guardian Nestable Sharps containers in:

- Intended Use
- Target Population
- Materials
- Design
- Performance testing

Sharps Away Disposable Sharps Container introduces no new questions concerning the safety or effectiveness of the Sharps Away disposable container and is thus substantially equivalent to the predicate device.

Performance Testing
Puncture Resistance – 49 CFR; Section 178.609(h)(2); ASTM 07P1152/ ASTM F2132-01 – Passed

Leak Resistance Test -Passed

Impact Test-Passed

Handle Test - Passed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

Solutions, Incorporated
Mr. Jeff D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K072667
Trade/Device Name: Sharps Away Disposable Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: October 4, 2007
Received: October 9, 2007

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

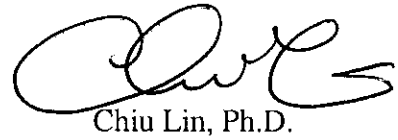
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072667

Device Name: *Sharps Away Disposable Container*

Indications for Use:

Sharps Away Disposable Containers and accessories are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps.

There are fourteen (14) containers and four (4) holders included in this submission. The model number, size, color and syringe size specification of each container and holder are as follows: (See attached sheet.)

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____√___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072667

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Indications for Use

Product specifications

Item #	Size	Color	Syringe Size
1901	1 Quart	Red	.5ml – 20ml
1902	1 Quart	Yellow	.5ml – 20ml
1903	2 Quart	Red	.5ml – 60ml
1904	2 Quart	Yellow	.5ml – 60ml
1905	5 Quart	Red	.5ml – 60ml
1906	5 Quart	Yellow	.5ml – 60ml
1907	2.5 Gal w/Horizontal Lid	Red	.5ml – 60ml
1908	2.5 Gal w/Horizontal Lid	Yellow	.5ml – 60ml
1909	2.5 Gal w/Vertical Lid	Red	.5ml – 60ml
1910	2.5 Gal w/Vertical Lid	Yellow	.5ml – 60ml
1911	6 Gal	Red	.5ml – 60ml
1912	6 Gal	Yellow	.5ml – 60ml
1915	.5 Quart	Red	Needles only
1916	.5 Quart	Yellow	Needles only
1951	2 Quart Wall Bracket	Beige	N/A
1952	5 Quart Wall Bracket	Beige	N/A
1953	2.5 Gal Wall Bracket	Beige	N/A
1954	1 Quart Countertop Holder	Blue	N/A